UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Brittany J. Buckley,	**Court File No.**
Plaintiff,	
	COMPLAINT WITH JURY DEMAND
vs.	
Hennepin County; Hennepin Healthcare System, Inc.; Hennepin Healthcare Research Institute; Paramedics Anthony D'Agostino, Katherine A. Kaufmann, and Jonathan R. Thomalia, all in their individual and official capacities; William Heegaard, MD, Jon Cole, MD, Jeffrey Ho, MD, Paul Nystrom, MD, Craig Peine, MD, Karen Heim-Duthoy, PharmD, and Researches J. Does 1-10, whose identities are presently unknown to Plaintiff, all in their individual and official capacities,	
Defendants.	

INTRODUCTION

1. This is an action for money damages brought pursuant to 42 U.S.C. §§ 1983, and under the common law of the State of Minnesota.
2. It is alleged that Defendants violated Plaintiff's constitutional rights under the Fourth and Fourteenth Amendments to the United States Constitution and engaged in medical malpractice, battery, and negligence under Minnesota state law.

JURISDICTION

3. Jurisdiction is based upon 28 U.S.C. §§ 1331 and 1343, and on the pendent jurisdiction of this Court to entertain claims arising under state law pursuant to 28 U.S.C. § 1367.

VENUE

4. This Court is the proper venue for this proceeding under 28 U.S.C. § 1391, as the material events and occurrences giving rise to Plaintiff's cause of action occurred within the State of Minnesota.

PARTIES

5. Plaintiff Brittany J. Buckley was at all material times a resident of the State of Minnesota, and of full age.
6. Defendant Hennepin County is a Minnesota municipal corporation that owns and operates Defendants Hennepin Healthcare System, Inc., and Hennepin Healthcare Research Institute. Defendant Hennepin County is being sued directly and also on the theories of respondeat superior or vicarious liability and pursuant to Minn. Stat. § 466.02, for the actions of its officers and officials.
7. Defendant Hennepin Healthcare System, Inc., formerly Hennepin County Medical Center, is a subsidiary corporation of Hennepin County and the public employer of the individually named and J. Doe Defendants. Defendant Hennepin Healthcare System, Inc., is sued directly and also on the theories of respondeat superior or vicarious liability and pursuant to Minn. Stat. § 466.02, for the actions of its employees and officials.
8. Defendant Hennepin Healthcare Research Institute, formerly Minneapolis Medical Research Institute, supports and oversees the medical research conducted at Hennepin Healthcare System, Inc., and operates the Office for Human Subjects Research/Institutional Review Board ("IRB") for Hennepin Healthcare System, Inc. Defendant Hennepin Healthcare Research Institute is sued directly and also on the theories of respondeat superior or vicarious liability and pursuant to Minn. Stat. § 466.02, for the actions of its employees and officials.

9. Defendant Paramedics Anthony D'Agostino, Katherine A. Kaufmann, and Jonathan R. Thomalia were at all times relevant to this complaint duly appointed and acting employees of Defendant Hennepin Healthcare System, Inc., acting under color of law, to wit, under color of the statutes, ordinances, regulations, policies, customs and usages of the State of Minnesota and/or Hennepin County. Defendants Anthony D'Agostino, Katherine A. Kaufmann, and Jonathan R. Thomalia are being sued in their individual and official capacities.

10. Defendants William Heegaard, MD, Jon Cole, MD, Jeffrey Ho, MD, Paul Nystrom, MD, Craig Peine, MD, Karen Hein-Duthoy, PharmD, and Researchers J. Does 1-10 were at all times relevant to this complaint duly appointed and acting employees of Defendant Hennepin County, and/or Hennepin Healthcare System, Inc., and/or Hennepin Healthcare Research Institute, acting under color of law, to wit, under color of the statutes, ordinances, regulations, policies, customs and usages of the State of Minnesota and/or Hennepin County.

    a. Defendant Dr. Heegaard is the Chief Medical/Clinical Officer for Hennepin Healthcare, Inc.

    b. Defendant Dr. Cole is the Chair of the Pharmacy and Therapeutics Committee for Hennepin Healthcare, Inc.

    c. Defendant Dr. Ho is the Chief Medical Director for Hennepin Healthcare, Inc., Emergency Medical Services (EMS).

    d. Defendant Dr. Nystrom is the Assistant Chief Medical Director for Hennepin Healthcare, Inc., Emergency Medical Services (EMS).

    e. Defendant Dr. Peine is the Chair of the Office of Human Subjects Research/IRB.

f. Defendant Dr. Hein-Duthoy is the Vice Chair of the Office of Human Subjects Research/IRB.

g. Defendants J. Does 1-10, whose true identities are presently unknown to Plaintiff, were at all relevant times employed by Defendant Hennepin County, and/or Hennepin Healthcare System, Inc., and/or Hennepin Healthcare Research Institute.

Defendants William Heegaard, MD, Jon Cole, MD, Jeffrey Ho, MD, Paul Nystrom, MD, Craig Peine, MD, Karen Hein-Duthoy, PharmD, and Researchers J. Does 1-10 are being sued in their individual and official capacities.

FACTS

11. On December 16, 2017, Plaintiff Brittany J. Buckley was in her apartment, sleeping on her sofa. Ms. Buckley was depressed about the two-year anniversary of her father's death and had been drinking alcohol. Ms. Buckley's friend became concerned for her safety and called 911 to request a welfare check. He met Minneapolis police officers John Bennett and James Lynch at the door of Ms. Buckley's apartment complex and let them into the building and then inside Ms. Buckley's apartment.

12. Officers Bennett and Lynch spoke to Ms. Buckley for several minutes. At one point, an ambulance was called.

13. A short time later, Paramedics Anthony D'Agostino, Katherine A. Kaufmann, and Jonathan R. Thomalia arrived on the scene. After a brief conversation, Mr. D'Agostino decided that Ms. Buckley needed to go to the hospital. Ms. Buckley asked Mr. D'Agostino to leave her apartment. Mr. D'Agostino replied that she was going to need to come with the ambulance

crew to the hospital. When Ms. Buckley verbally objected, Mr. D'Agostino stated that she was on a medical transportation hold and would have to come with them.

14. Ms. Buckley continued to verbally object while the officers and paramedics stood her on her feet, handcuffed her behind her back, and carried her out of the building and into the ambulance. Ms. Buckley never attempted to kick, strike, or bite anyone as she was being carried out to the ambulance.

15. Once in the ambulance, Ms. Buckley was laid face down, legs bent up with feet to her buttocks. Although verbally complaining and crying, she showed no signs of physical resistance. Ms. Buckley was then rolled onto her back, both arms cuffed to the gurney and strapped down by shoulder harness and hip, thigh, and ankle straps. Ms. Buckley continued to show no signs of physical resistance or aggression and did not push against the restraints.

16. Despite Ms. Buckley's lack of physical resistance or aggression, the ambulance run report falsely states, "Patient attempted kicking, biting and head butting responders while she was being removed from her house and taken to the ambulance." The report further falsely states, "Patient continued to fight the restraints…" and then adds "it was elect[ed to] enroll her into the ketamine trials."

17. The "ketamine trials" was a study called "Ketamine versus Midazolam for Prehospital Agitation." This study was the second of two Hennepin County studies attempting to validate the use of ketamine by ambulance crews to sedate patients whom paramedics deemed agitated. In this study, agitation was defined as "a state of extreme emotional disturbance where patients become physically aggressive or violent, endangering themselves or those caring for them." (Exhibit 1.)

18. The prior study, *A Prospective Study of Ketamine versus Haloperidol for Severe Prehospital Agitation*, involved assessment of patients by paramedics against an Altered Mental Status Scale (AMSS), a measurement tool used internally by researchers at Hennepin Healthcare Systems, Inc., based on a combination of other scales used to measure alertness, sedation, agitation or intoxication. As outlined in this study, this scale measures agitation as follows:

Table 1. The altered mental status scale.

Score	Responsiveness	Speech	Facial Expression	Eyes
+4	Combative, very violent, or out of control	Loud outbursts	Agitated	Normal
+3	Very anxious, agitated, mild physical element of violence	Loud outbursts	Agitated	Normal
+2	Anxious, agitated	Loud outbursts	Normal	Normal
+1	Anxious, restless	Normal	Normal	Normal
0	Responds readily to name in normal tone	Normal	Normal	Clear, no ptosis
−1	Lethargic response to name	Mild slowing or thickening	Mild relaxation	Glazed or mild ptosis (<half eye)
−2	Responds only if name is called loudly	Slurring or prominent slowing	Marked relaxation (slacked jaw)	Glazed and marked ptosis (>half eye)
−3	Responds only after mild prodding	Few recognizable words	Marked relaxation (slacked jaw)	Glazed and marked ptosis (>half eye)
−4	Does not respond to mild prodding or shaking	Few recognizable words	Marked relaxation (slacked jaw)	Glazed and marked ptosis (>half eye)

Although the purpose of this study was to examine ketamine as a treatment for severe agitation of +4 on the AMS scale (Exhibit 2, p. 1), those patients were excluded from the study and were all treated with ketamine. Instead, patients rated +2 or +3 on the AMS scale were injected with haloperidol during one six-month period of the study, and patients rated +2 or +3 on the AMS scale were injected with ketamine during another six-month period of the study. Alternative sedatives were removed from the ambulances and the drug administered to these patients was dictated solely by the time period during which they were enrolled into the study rather than any medical judgment on the part of caregivers. (Exhibit 2.)

19. The article, *A Prospective Study of Ketamine versus Haloperidol for Severe Prehospital Agitation*, (Exhibit 2), reported the results of the study on patients rated +2 and +3 on the AMS scale. Defendants Dr. Cole, Dr. Nystrom, and Dr. Ho reported that 49% of patients receiving ketamine suffered complications as opposed to only 5% of patients receiving haloperidol, the long-time standard treatment for agitation. Complications in the ketamine

group included hypersecretion/hypersalivation, emergence reaction (nightmares and hallucinations), vomiting, dystonia (abnormal muscle movements), laryngospasm, and akathisia (inner restlessness and inability to remain still). Defendants further reported, "Intubation rate was also significantly higher in the ketamine group; 39% (25/64) of patients receiving ketamine were intubated vs. 4% (3/82) of patients receiving haloperidol . . . ." On April 21, 2016, Defendants published the following conclusion: "Ketamine is superior to haloperidol in terms of time to adequate sedation for severe prehospital . . . agitation, but it is associated with more complications and a higher intubation rate." (Exhibit 2.)

20. "Intubation," also known as "endotracheal intubation" is a serious medical procedure which involves placing a tube into the trachea (airway) in order to facilitate ventilation of patients experiencing difficulty breathing. While it is vital to manage the airways of patients experiencing breathing difficulties and endotracheal intubation is considered the gold standard for airway management, endotracheal intubation is itself associated with a variety of minor to life-threatening complications. These complications range from hoarseness and sore throat to trauma to mouth structures and larynx to spinal cord injury and other serious nerve damage. (See Exhibit 3, *Complications of Endotracheal Intubation and Other Airway Management Procedures*.)

21. In a subsequent article on Defendants' ketamine versus haloperidol study, "*A Prospective Study of Ketamine as Primary Therapy for Prehospital Profound Agitation*," patients rated +4 were included in the reported data. There, Defendants Dr. Cole, Dr. Nystrom, and Dr. Ho reported that endotracheal intubation rate for patients receiving ketamine was 57% (28/49 patients enrolled into the study were intubated). (Exhibit 4.)

22. The issue of high rates of endotracheal intubation in patients receiving ketamine for prehospital agitation was well-known to Defendants before they began even their first study as this issue was being discussed and debated in journal articles published prior to the first study and Defendants participated in the discussions through their own journal articles. For example, a 2012 article authored by Defendants Dr. Cole, Dr. Heegaard, Dr. Nystrom, and Dr. Ho reported on two patients who were diagnosed with Excited Delirium Syndrome (ExDS) and treated with ketamine. In that article, Defendants published the following warning: "We would caution against using ketamine sedation in situations that do not warrant the immediate need for interruption of the severe, life-threatening, metabolic acidosis/catecholamine surge crisis seen in late-stage ExDS. Clinicians should always consider the risk-benefit ratio of a possible intervention. In 2012, Burnett et al. described a case report of laryngospasm as a complication of prehospital ketamine administration in an agitated person [reference removed]. Laryngospasm is a known potential side effect of ketamine and can cause airway compromise." Defendants further stated, "We would advocate that ketamine not be the chemical solution for every unruly or belligerent subject[], as this would lead to overuse with unnecessary risk." In sharing their facility's protocol for prehospital agitation, Defendants stated, "Our EMS system standing-order protocol reserves the use of ketamine for profound agitation involving the imminent risk of injury to the patient or provider . . . ." (Exhibit 5, *Successful Management of Excited Delirium Syndrome with Prehospital Ketamine: Two Case Examples*.) Thus, Defendants knew of and personally acknowledged the risks associated with ketamine, specifically the complication involving "airway compromise," as far as five years prior to December, 2017.

23. Researchers at other institutions shared similar concerns with high rates of endotracheal intubation after prehospital ketamine administration for agitation. *The Use of Prehospital Ketamine for Control of Agitation in a Metropolitan Firefighter-based EMS System*, (Exhibit 6), was published on August 25, 2014, and reported a 23% endotracheal intubation rate for patients receiving ketamine. The first study of prehospital ketamine use on agitated patients by Defendants was commenced in October, 2014, after the above results were published and after Defendants Dr. Cole and Dr. Heegaard themselves acknowledged the high intubation rates associated with use of ketamine on agitated patients back in 2012. Thus, Defendants knew, prior to commencement of the first study and especially prior to commencement of the second study, that high rates of endotracheal intubation were a known, reported, and serious risk for agitated people treated with ketamine.

24. The second study by Defendants commenced on August 1, 2017, and was scheduled to be completed by August 31, 2018, but was suspended in July 2018 after widespread media exposure and resulting complaints by the community. As in the first study, subjects were enrolled without their knowledge or consent and the drug administered to these patients was dictated solely by the time period during which they were enrolled into the study. The study protocol precluded the use of other medications, including haloperidol, which the first study already demonstrated was far safer than ketamine.

25. Both studies were approved by Defendant Hennepin Healthcare Research Institute, then known as Minneapolis Medical Research Institute, the internal IRB for Hennepin Healthcare Systems, Inc. Despite the known risks of high endotracheal intubation rates and other complications with ketamine compared to the standard treatment with haloperidol, the IRB approved these studies as "Waiver of Consent Research" pursuant to 45 C.F.R. § 46.116(d).

26. Department of Health and Human Services regulation 45 C.F.R. § 46.116 addresses requirements for informed consent of human subjects in medical research. The law is stringent, stating "[e]xcept as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative" and outlines specific information to be provided along with procedural safeguards to protect the rights and well-being of potential research subjects.

27. There are narrow exceptions that allow an IRB to waive the requirement for researchers to obtain informed consent prior to including a human subject in a research study. Defendant Hennepin Healthcare Research Institute waived the prior informed consent requirement for both ketamine studies based on the Waiver of Consent provision 45 C.F.R. § 46.116 (d), which states as follows:

> (d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:
>
> (1) The research involves no more than minimal risk to the subjects;
> (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
> (3) The research could not practicably be carried out without the waiver or alteration; and
> (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

28. "Minimal risk," fur purposes of section 46.116(d), is defined as follows: "Minimum risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." 45 C.F.R. § 46.102(i). Sedation with ketamine coupled with endotracheal intubation is not a harm or

discomfort ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. The high risk of endotracheal intubation in the use of ketamine for treatment of agitation falls far outside the threshold for "minimal risk." Further, the potential complications stemming from endotracheal intubation have the potential to affect the rights and welfare of study subjects. Thus, Defendants knowingly violated 45 C.F.R. § 46.116 (d) when they waived consent for both ketamine studies.

29. Through her encounter with Defendant Hennepin Healthcare System, Inc. and Defendant Paramedics Anthony D'Agostino, Katherine A. Kaufmann, and Jonathan R. Thomalia, Ms. Buckley was unwittingly enrolled into the second ketamine study, *Ketamine Versus Midazolam for Prehospital Agitation*, without consent. Despite claims in the ambulance run record that Ms. Buckley was physically combative, she was scored by these same paramedics at the beginning of their care as +2 on the AMS scale at time mark 14:57:49. The +2 score includes vocal outbursts but no physical resistance.

30. In addition to the use of their internal Altered Mental Status Scale (AMSS), paramedics routinely use the Glasgow Coma Scale (GCS) to measure the level of consciousness of a patient. It is comprised of a score of best eye response (1-4 points), best verbal response (1-5 points, and best motor response (points 1-6). A GCS score of 15 indicates a fully awake and alert individual. At time mark 14:57:49, when paramedics scored Ms. Buckley as +2 on the AMS scale, they also scored her as 15 on the GCS scale.

31. As Defendant Paramedics Anthony D'Agostino, Katherine A. Kaufmann, and Jonathan R. Thomalia drew up medication in a syringe, Ms. Buckley saw that she was about to be injected with an unknown medication and verbally objected. She told the Defendant

Paramedics that she did not want whatever drug they were about to inject into her body. She was verbally objecting but not physically resisting.

32. At time mark 15:00:00, before Defendant Paramedics could inject her with ketamine, Ms. Buckley's AMSS score spontaneously dropped to -2 (responds only if name is called loudly, slurring or prominent slowing of speech, marked relaxation, and glazed or marked ptosis (eyelid drooping)). Her GCS score also dropped to 7.

33. Despite Ms. Buckley's only partially conscious state and AMSS score of -2, at time mark 15:00:17, she was injected with 150 mg of ketamine without consent and in direct disregard for her verbal requests not to be medicated. She immediately developed complications including altered mental status, bradypnea (abnormally slow breathing), respiratory distress, and tachycardia (abnormally rapid heart rate).

34. At time mark 15:02:00, Ms. Buckley's AMSS score was measured at -4 (unresponsive to physical stimuli) and GCS was measured at 3 (does not open eyes, makes no sounds, makes no movements). Her respiratory distress continued to worsen and, by 15:08:00, paramedics were manually ventilating her with a bag-valve-mask device and her heart rate remained extremely rapid. Ms. Buckley also experienced hypersalivation requiring suction and administration of atropine to remove the excess secretions that interfered with her breathing.

35. Upon arrival at the Hennepin County Medical Center, one of Ms. Buckley's diagnoses was acute hypoxic (low oxygen) respiratory failure due to ketamine injection and she was intubated shortly after arrival. She remained intubated until the next day.

36. Ms. Buckley awoke to find that someone had left a document in her room entitled *Consent for Clinical Investigation Conducted with Patients Notification of Enrollment*. (Exhibit 7.) It

was only through this document that she learned she had been enrolled into the study *Ketamine versus Midazolam for Prehospital Agitation*.

37. Body-worn camera recordings by Officers John Bennett and James Lynch and the ambulance run record created by Defendant Paramedics Anthony D'Agostino, Katherine A. Kaufmann, and Jonathan R. Thomalia show that Ms. Buckley engaged in verbal outbursts but was not physically aggressive or combative. Shortly after securing and physically restraining her inside the ambulance, Defendant Paramedics scored Ms. Buckley at -2 on the AMS scale. Thus, there was no need to sedate Ms. Buckley at all. Because Defendant Paramedics Anthony D'Agostino, Katherine A. Kaufmann, and Jonathan R. Thomalia had already determined that Ms. Buckley would be enrolled into the ketamine study, she was administered ketamine even as she drifted into unconsciousness. She then developed a well-known complication of ketamine administration—respiratory failure requiring endotracheal intubation, with its potential risks and dangers.

38. In June of 2018, after a public outcry and in an attempt to restore the public's trust, Defendants Dr. Ho and Dr. Nystrom published an opinion article in the Minneapolis Star Tribune entitled, "Counterpoint: Discussion of ketamine use on suspects is incomplete." In this article, Defendants stated that, "of the available sedatives in our EMS system, ketamine is often the best **choice** based on the patient's behavior, the severity of agitation, the timing, the risk of a patient causing self-injury even after physical restraints have been applied and other medical considerations." (emphasis added). Defendants' classification of ketamine as often being "the best choice" is peculiar as both studies, by design, deprived the paramedics of the ability to make a "choice" by removing all but one type of sedative from the ambulances. Defendants' sudden enthusiasm for routine use of ketamine is further

contradicted by their own published research, where Defendants explicitly cautioned against overuse of ketamine and advocated for its use only in exceptional situations involving patients suffering from Excited Delirium Syndrome (ExDS) who are engaged in active physical violence and aggression.

39. Prior to August of 2017, Hennepin Healthcare paramedics did have a choice – they could choose an appropriate sedative, including ketamine, depending on the circumstances of each case. Although ketamine was available, its use was restricted to "profoundly agitated [patients] with physical violence." (Exhibit 5.) In fact, as Defendants themselves reported, Hennepin County's "EMS system standing-order protocol reserve[d] the use of ketamine for profound agitation involving imminent risk of injury to patient or provider." (Exhibit 5.) Defendants themselves "cautioned against using ketamine sedation in situations that do not warrant the immediate need for interruption of the severe, life-threatening, metabolic acidisis/catecholamine crisis seen in late-stage ExDS." (Exhibit 5.) Defendants emphasized that "[c]linicians should always consider the risk-benefit ratio of a possible [ketamine] intervention" and further "advocate[d] that ketamine not be the chemical solution for every unruly or belligerent subject[], as this would lead to overuse with unnecessary risk." (Exhibit 5.)

40. Upon information and belief, prior to August 1, 2017, Defendants' standard operating procedure/protocol for treatment of severe agitation was to treat acute undifferentiated agitation with intramuscular haloperidol. But, in August of 2017, Defendants abandoned their own reported scientific conclusions and changed the sedation protocol in a way that eliminated choice and mandated sedation with ketamine for all agitated patients despite their level of agitation. Most strikingly, while Defendants previously prohibited use of ketamine

unless the patient exhibited physical violence, the new protocol mandated use of ketamine on patients, such as Plaintiff, who exhibited loud verbal outbursts with no physical aggression. Furthermore, while Defendants previously advocated for use of risk-benefit analysis prior to administration of ketamine, (Exhibit 5), Defendants' new protocol disposed even with this precaution, leaving ketamine as the only choice of sedative available to the paramedics.

41. Defendants previously publicly acknowledged that using ketamine to sedate every patient who needed sedation "would lead to overuse with unnecessary risk." (Exhibit 5.) Yet, from August 1, 2017, to January 31, 2018, Defendants made a knowing and conscious decision to sedate every patient who needed sedation with ketamine and to deprive the paramedics of the opportunity to use risk-benefit analysis to choose an appropriate sedative given the circumstances. Defendants knew, from their own prior research, that approximately 49% of patients (about 5 out of 10) sedated with ketamine during this period would develop complications. Defendants further knew, from their own prior research, that approximately 39% of patients (about 4 out of 10) sedated with ketamine during this period would develop respiratory distress and require intubation.

42. Despite these known risks and availability of haloperidol, Defendants implemented a new sedation protocol from August 1, 2017, to January 31, 2018, which required Hennepin Healthcare paramedics to sedate all patients needing sedation with ketamine without the patients' consent. On December 16, 2017, as part of this new protocol, Defendants subjected Plaintiff to involuntary and nonconsensual sedation with ketamine which, predictably, resulted in complications, respiratory distress, and subsequent endotracheal intubation.

43. As a direct result of Defendants' actions, Plaintiff suffered involuntary and unnecessary sedation with ketamine, severe physical pain and discomfort, long-term chest pain and

bruising, long-term throat pain, long-term voice changes and hoarseness, stress, fear, shame, humiliation, embarrassment, diminished self-esteem, diminished quality and enjoyment of life, and severe mental/emotional trauma, anguish, and distress.

CLAIMS FOR RELIEF

COUNT 1: 42 U.S.C. § 1983 – FOURTH AND/OR FOURTEENTH AMENDMENT EXCESSIVE FORCE AGAINST ALL INDIVIDUAL DEFENDANTS IN THEIR INDIVIDUAL CAPACITIES

44. Paragraphs 1 through 43 are incorporated herein by reference as though fully set forth.

45. Based on the above factual allegations, Defendants D'Agostino, Kaufmann, and Thomalia, through their actions, acting under the color of state law, engaged in excessive use of force against Plaintiff when they injected Plaintiff with ketamine without consent or justification.

46. Defendants Heegaard, Cole, Ho, Nystrom, Peine, Heim-Duthoy, and J. Does 1-10 are also liable for the excessive use of force against Plaintiff because they intentionally developed and implemented a facility-wide ketamine policy/protocol which, by design, resulted in unnecessary and unjustified sedation of patients with ketamine.

47. As a result of these constitutional violations, Plaintiff suffered damages as aforesaid.

COUNT 2: 42 U.S.C. § 1983 – FOURTEENTH AMENDMENT DELIBERATE INDIFFERENCE AND BODILY INTEGRITY VIOLATIONS AGAINST ALL INDIVIDUAL DEFENDANTS IN THEIR INDIVIDUAL CAPACITIES

48. Paragraphs 1 through 43 are incorporated herein by reference as though fully set forth.

49. Based on the above factual allegations, Defendants, through their actions, acting under the color of state law, violated Plaintiff's constitutional right to substantive due process of law under the Fourteenth Amendment to the United States Constitution through their deliberate indifference towards significant risk of harm to Plaintiff and through their violation of Plaintiff's constitutional right to bodily integrity.

50. Defendants D'Agostino, Kaufmann, and Thomalia unnecessarily and without consent or justification sedated Plaintiff with ketamine while Plaintiff was fully restrained and while Plaintiff was semi-conscious and offering no physical resistance. Defendants knew, when they administered the ketamine, that there was a substantial risk that Plaintiff would develop respiratory difficulties and require intubation but Defendants ignored these risks and injected Plaintiff with ketamine anyway. Defendants physically intruded into Plaintiff's body without her consent and, despite her objections and refusal, subjected Plaintiff to unwanted medical treatment which carried significant risk of complications.

51. Defendants Heegaard, Cole, Ho, Nystrom, Peine, Heim-Duthoy, and J. Does 1-10 are also liable to Plaintiff for deliberate indifference and violation of bodily integrity because they intentionally developed and implemented a facility-wide ketamine policy/protocol which, by design, resulted in unnecessary and unjustified sedation of patients with ketamine. Defendants' ketamine policy/protocol deprived individual paramedics of the ability to use medical judgment/discretion to determine whether sedation was necessary and, if so, which sedative was appropriate under the circumstances. Defendants' ketamine policy/protocol furthermore mandated that all patients needing sedation be sedated with ketamine and prohibited paramedics from using safer and equally effective alternative sedatives, such as haloperidol.

52. The Defendants' actions against Plaintiff, as outlined above, are shocking to the conscience.

53. As a result of these constitutional violations, Plaintiff suffered damages as aforesaid.

COUNT 3: 42 U.S.C. § 1983 – FOURTH AND FOURTEENTH AMENDMENT (*MONELL*) VIOLATIONS AGAINST HENNEPIN COUNTY, HENNEPIN HEALTHCARE SYSTEM, INC., HENNEPIN HEALTHCARE RESEARCH INSTITUTE, AND ALL INDIVIDUAL DEFENDANTS IN THEIR OFFICIAL CAPACITIES

54. Paragraphs 1 through 43 are incorporated herein by reference as though fully set forth.

55. Prior to December of 2017, Defendants developed and maintained policies and/or customs exhibiting deliberate indifference towards the constitutional rights of persons in Hennepin County or in the custody of Hennepin County, which caused the violations of Plaintiff's constitutional rights.

56. Specifically, Defendants developed and implemented a county-wide protocol which mandated and encouraged unnecessary sedation of patients with ketamine. Defendants' ketamine protocol mandated sedation of patients who did not need to be sedated and encouraged individual paramedics to sedate patients, such as Plaintiff, who were fully restrained, semi-conscious, and not engaged in physical resistance or aggression.

57. Defendants removed all other sedatives from their ambulances, thereby depriving Hennepin County paramedics of the ability to rely on medical/professional judgment as to what type of sedative may be appropriate under the circumstances.

58. Defendants' ketamine protocol required paramedics to sedate patients without their consent and to subject patients to high-risk, unnecessary medical treatment, all for the sake of medical research. In developing this new protocol, Defendants intentionally disregarded and violated federal informed-consent regulations which were enacted by the federal government to protect the public from abusive and unethical medical research.

59. Defendants knew of the significant, common, and life-threatening complications associated with ketamine, especially the high percentage of patients who suffer respiratory distress and require intubation following ketamine injection, yet Defendants implemented a policy that

left paramedics with no other alternative but to use ketamine, even for patients who were only mildly agitated and not exhibiting any physical resistance or aggression. Defendants knew that haloperidol was a much safer and equally effective sedative for mildly agitated patients, yet Defendants removed haloperidol from the ambulances and instructed paramedics to instead sedate mildly agitated patients with ketamine.

60. These policies and/or customs were the cause of the violations of Plaintiffs' constitutional rights alleged herein.

COUNT 4: MEDICAL MALPRACTICE AGAINST ALL DEFENDANTS UNDER MINNESOTA STATE LAW

61. Paragraphs 1 through 43 are incorporated herein by reference as though fully set forth.

62. Based on the above factual allegations, the individual Defendants have committed medical malpractice against Plaintiff. Specifically, Defendants breached a recognized duty and standard of care when they sedated Plaintiff with ketamine while Plaintiff was fully restrained and while Plaintiff was semi-conscious and offering no physical resistance and when they subjected Plaintiff to unnecessary and invasive high-risk medical treatment without her consent. Defendants also breached a recognized duty and standard of care when they developed and implemented a county-wide protocol which encouraged unnecessary sedation with ketamine and which ultimately caused Plaintiff to be sedated with ketamine without justification.

63. As a direct and proximate result of Defendants' malpractice, Plaintiff suffered injuries and damages as aforesaid.

64. Defendants Hennepin County, Hennepin Healthcare System, Inc., and Hennepin Healthcare Research Institute are vicariously liable for the malpractice of the individual Defendants.

COUNT 5: BATTERY AGAINST ALL DEFENDANTS UNDER MINNESOTA STATE LAW

65. Paragraphs 1 through 43 are incorporated herein by reference as though fully set forth.

66. Based on the above factual allegations, Defendants battered Plaintiff. Specifically, Defendants engaged in intentional, offensive, and unpermitted contact with Plaintiff when they sedated her with ketamine without justification and without consent and when they ignored and disregarded Plaintiff's objection and refusal as to the injection.

67. As a direct and proximate result of Defendants' battery, Plaintiff suffered damages as aforesaid.

68. Defendants Hennepin County, Hennepin Healthcare System, Inc., and Hennepin Healthcare Research Institute are vicariously liable for the battery of the individual Defendants.

COUNT 6: NEGLIGENCE PER SE AGAINST ALL DEFENDANTS UNDER MINNESOTA STATE LAW

69. Paragraphs 1 through 43 are incorporated herein by reference as though fully set forth.

70. Based on the above factual allegations, Defendants committed negligence per se. Specifically, Defendants breached federal regulation 45 C.F.R. § 46.116, which prohibits subjecting human subjects to medical research/experiments/studies without informed consent unless the medical research/experiment/study involves no more than "minimal risk" to the human subject.

71. "Minimal risk," in turn, is defined as follows: "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." 45 C.F.R. § 46.102(i).

72. Intramuscular injection with ketamine for purposes of sedation, coupled with its known and high-risk complication of respiratory distress and subsequent intubation, clearly involves

more than "minimal risk" to the human subject being sedated. Furthermore, Defendants knew, prior to subjecting Plaintiff to injection with ketamine and entering her into their study, that there was a 49% likelihood that Plaintiff would develop general complications from ketamine and that there was a 39% likelihood that Plaintiff would develop respiratory distress requiring intubation.

73. Plaintiff was within the intended protection of section 46.116, and the harm suffered by the Plaintiff is of the type this regulation was intended to prevent.

74. As a direct and proximate result of this negligence per se, Plaintiff suffered damages as aforesaid.

75. Defendants Hennepin County, Hennepin Healthcare System, Inc., and Hennepin Healthcare Research Institute are vicariously liable for the negligence of the individual Defendants.

RELIEF REQUESTED

WHEREFORE, Plaintiff requests that this Court grant the following relief:

a. Issue an order granting Plaintiff judgment against Defendants, finding that Defendants violated Plaintiff's constitutional rights under the Fourth and Fourteenth Amendments to the United States Constitution and that Defendants are liable to Plaintiff for all damages resulting from these violations;

b. Issue an order granting Plaintiff judgment against Defendants, finding that Defendants committed medical malpractice, battery, and negligence against Plaintiff under Minnesota state law and that Defendants are liable to Plaintiff for all damages resulting from these violations;

c. Award of compensatory damages to Plaintiff against all Defendants, jointly and severally;

d. Award of punitive damages to Plaintiff against all Defendants, jointly and severally;

e. Award of reasonable attorney's fees and costs to Plaintiff pursuant to 42 U.S.C. § 1988;

f. Award of such other and further relief as this Court may deem appropriate.

THE PLAINTIFF HEREBY DEMANDS A JURY TRIAL

THE LAW OFFICE OF ZORISLAV R. LEYDERMAN

Dated: November 7, 2018

By: s/ Zorislav R. Leyderman

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